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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Jan BATZER et al.

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Serial No. : 10/824,102

Examiner: Webb, Walter E

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For : COSMETIC OR DERMATOLOGICAL ACTIVE INGREDIENT COMBINATION

AMENDMENT UNDER 37 C.F.R. § 1.111

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Amendment
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

This is in response to the Office Action mailed from the U.S. Patent and Trademark Office on December 29, 2010, which sets a three-month shortened statutory period for reply to expire on March 29, 2011. Applicants hereby request an extension of time for one month and are concurrently filing a formal Request for Extension of Time, together with all requisite fees therefor. If for any reason the Request for Extension of Time is not associated with the file, or the fee submitted herewith is deemed insufficient for any reason, the present submission should be interpreted to include the requisite Request for Extension of Time, and the Patent and Trademark Office is hereby authorized to charge any fees necessary to preserve the pendency of this application to deposit account No. 19-0089.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks/Arguments begin on page 11 of this paper.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. - 110. (cancelled)

111. (new) A cosmetic or dermatological preparation, wherein the preparation comprises 8-hexadecene-1,16-dicarboxylic acid and at least one antioxidant.

112. (new) The preparation of claim 111, wherein the at least one antioxidant is selected from imidazoles, peptides, carotenoids, α-lipoic acid, lipoamide, aurothioglucose, propylthiouracil, metal chelators, humic acid, bile acid, bile extracts, bilirubin, biliverdin, unsaturated fatty acids, folic acid, flavenoids, tocopherols, rutinic acid, ferulic acid, butylhydroxytoluene, butylhydroxyanisole, nordihydroguaiaretic acid, nordihydroguaiaretic acid, trihydroxybutyrophenone, kojic acid, uric acid, mannose, zinc and salts thereof, selenium compounds and enzymatic antioxidants.

113. (new) The preparation of claim 111, wherein the at least one antioxidant comprises at least one of tocopherol and a derivative thereof.

114. (new) The preparation of claim 113, wherein the at least one antioxidant comprises tocopherol acetate.

115. (new) The preparation of claim 114, wherein the preparation further comprises uric acid.

116. (new) The preparation of claim 114, wherein the preparation further comprises α-lipoic acid.

117. (new) The preparation of claim 114, wherein the preparation further comprises carnosine.

118. (new) The preparation of claim 114, wherein the preparation further comprises a ubiquinone.

119. (new) The preparation of claim 118, wherein the ubiquinone comprises coenzyme Q10.

120. (new) The preparation of claim 114, wherein the preparation further comprises tyrosine or a salt or derivative thereof.

121. (new) The preparation of claim 111, wherein the preparation is present as a W/O emulsion.

122. (new) The preparation of claim 111, wherein the preparation further comprises at least one UV filter substance.

123. (new) The preparation of claim 121, wherein the at least one UV filter substance comprises

2,4-bis-(4-(2-ethylhexyloxy)-2-hydroxyphenyl)-6-methoxyphenyl)-1,3,5-triazine.

124. (new) The preparation of claim 111, wherein the at least one antioxidant is present in a concentration of from 0.001% to 30% by weight, based on a total weight of the preparation.

125. (new) The preparation of claim 124, wherein the at least one antioxidant is present in a concentration of from 0.1% to 10% by weight.

126. (new) The preparation of claim 111, wherein the 8-hexadecene-1,16-dicarboxylic acid is present in a concentration of from 0.001% to 10% by weight, based on a total weight of the preparation.

127. (new) The preparation of claim 126, wherein the 8-hexadecene-1,16-dicarboxylic acid is present in a concentration of from 0.05% to 5% by weight.

128. (new) The preparation of claim 126, wherein the 8-hexadecene-1,16-dicarboxylic acid is present in a concentration of not more than 1.00 % by weight.

129. (new) A cosmetic or dermatological preparation, wherein the preparation comprises from 0.001% to 5% by weight of 8-hexadecene-1,16-dicarboxylic acid and from 0.05% to 20% by weight of at least one antioxidant, based on a total weight of the preparation.

130. (new) The preparation of claim 129, wherein the at least one antioxidant is selected from imidazoles, peptides, carotenoids, α-lipoic acid, lipoamide, aurothioglucose, propylthiouracil, metal chelators, humic acid, bile acid, bile extracts, bilirubin, biliverdin, unsaturated fatty acids, folic acid, flavenoids, tocopherols, rutinic acid, ferulic acid, butylhydroxytoluene, butylhydroxyanisole, nordihydroguaiaretic acid, nordihydroguaiaretic acid, trihydroxybutyrophenone, kojic acid, uric acid, mannose, zinc and salts thereof, selenium compounds and enzymatic antioxidants.

131. (new) The preparation of claim 129, wherein the at least one antioxidant comprises tocopherol acetate.

132. (new) The preparation of claim 131, wherein the preparation further comprises uric acid.

133. (new) The preparation of claim 131, wherein the preparation further comprises α-lipoic acid.

134. (new) The preparation of claim 131, wherein the preparation further comprises carnosine.

135. (new) The preparation of claim 131, wherein the preparation further comprises coenzyme Q10.

136. (new) The preparation of claim 131, wherein the preparation further comprises tyrosine or

a salt or derivative thereof.

137. (new) The preparation of claim 129, wherein the preparation is present as a W/O emulsion.

138. (new) The preparation of claim 129, wherein the preparation further comprises at least one UV filter substance that is liquid at room temperature.

139. (new) The preparation of claim 138, wherein the at least one UV filter substance comprises 2,4-bis-(4-(2-ethylhexyloxy)-2-hydroxyphenyl)-6-methoxyphenyl)-1,3,5-triazine.

140. (new) The preparation of claim 129, wherein the at least one antioxidant is present in a concentration of from 0.1% to 10% by weight.

141. (new) The preparation of claim 129, wherein the 8-hexadecene-1,16-dicarboxylic acid is present in a concentration of not more than 1.00 % by weight.

142. (new) A cosmetic or dermatological preparation, wherein the preparation is present as a W/O emulsion and comprises from 0.001% to 1.00% by weight of 8-hexadecene-1,16-dicarboxylic acid and from 0.05% to 20% by weight of one or more antioxidants which comprise at least one of tocopherol and a derivative thereof, based on a total weight of the preparation.

143. (new) The preparation of claim 142, wherein the one or more antioxidants comprise tocopherol acetate.

144. (new) The preparation of claim 143, wherein the preparation further comprises uric acid.

145. (new) The preparation of claim 143, wherein the preparation further comprises α-lipoic acid.

146. (new) The preparation of claim 143, wherein the preparation further comprises carnosine.

147. (new) The preparation of claim 143, wherein the preparation further comprises coenzyme Q10.

148. (new) The preparation of claim 143, wherein the preparation further comprises tyrosine or a salt or derivative thereof.

149. (new) The preparation of claim 143, wherein the preparation further comprises at least one UV filter substance that is liquid at room temperature.

150. (new) The preparation of claim 149, wherein the at least one UV filter substance comprises 2,4-bis-(4-(2-ethylhexyloxy)-2-hydroxyphenyl)-6-methoxyphenyl)-1,3,5-triazine.

151. (new) The preparation of claim 129, wherein the one or more antioxidants are present in a concentration of from 0.1% to 10% by weight.

152. (new) The preparation of claim 150, wherein the preparation further comprises uric acid.

153. (new) The preparation of claim 150, wherein the preparation further comprises α-lipoic acid.

154. (new) The preparation of claim 150, wherein the preparation further comprises carnosine.

155. (new) The preparation of claim 150, wherein the preparation further comprises coenzyme Q10.

156. (new) The preparation of claim 150, wherein the preparation further comprises tyrosine or a salt thereof.

157. (new) The preparation of claim 150, wherein the preparation further comprises octocrylene.

158. (new) The preparation of claim 111, wherein the preparation has a pH of from 5 to 7.

159. (new) The preparation of claim 111, wherein the preparation has a water content of from

50% to 90% by weight, based on a total weight of the preparation.

160. (new) The preparation of claim 129, wherein the preparation has a pH of from 5 to 7.

161. (new) The preparation of claim 160, wherein the preparation has a water content of from 50% to 90% by weight, based on a total weight of the preparation.

162. (new) The preparation of claim 142, wherein the preparation has a pH of from 5 to 7.

163. (new) The preparation of claim 162, wherein the preparation has a water content of from 50% to 90% by weight, based on a total weight of the preparation.

164. (new) The preparation of claim 143, wherein the preparation has a pH of from 5 to 7.

165. (new) The preparation of claim 164, wherein the preparation has a water content of from 50% to 90% by weight, based on a total weight of the preparation.

REMARKS

Entry of the foregoing amendments is respectfully requested.

Summary of Amendments

Upon entry of the foregoing amendments, claims 56-110 are cancelled and claims 111-165 are added, whereby claims 111-165 will be pending, with claims 111, 129 and 142 being independent claims.

Support for the new claims can be found throughout the present specification (see, e.g., the Examples thereof). Regarding the concentration of 8-hexadecene-1,16-dicarboxylic acid recited in, e.g., independent claim 142 it is noted that 1.00% by weight is the highest concentration of 8-hexadecene-1,16-dicarboxylic acid that is employed in any of the exemplified compositions.

Applicants point out that the cancellation of claims 56-110 is without prejudice or disclaimer, and Applicants expressly reserve the right to prosecute the subject matter of the cancelled claims in one or more continuation and/or divisional applications.

Summary of Office Action

Claims 58-73, 76, 80-95, 98-105 and 107-110 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 56, 57, 77-79, 96, 97 and 106 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Harding et al., U.S. Patent No. 5,705,144 (hereafter "HARDING") in view of Wenzel et al., U.S. Patent No. 6,143,532 (hereafter "WENZEL") as allegedly evidenced by

Science Lab.com (Chemicals & Laboratory Equipment).

Claims 74 and 75 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over HARDING in view of WENZEL and further in view of Nachbar et al., J Mol Med 1995: 73, pp.7-17 (hereafter "NACHBAR").

Claims 56 and 57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 44 and 55 of copending Application No. 11/087,395.

Claims 56, 57, 74, 75, 96 and 97 are rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1 and 17 of U.S. Patent No. 7,341,712.

Claims 56 and 57 are rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1 and 17 of U.S. Patent No. 7,820,177.

Response to Office Action

Reconsideration and withdrawal of the rejections of record are respectfully requested, in view of the foregoing amendments and the following remarks.

Response to Rejection under 35 U.S.C. § 103(a) over HARDING in view of WENZEL

Claims 56, 57, 77-79, 96, 97 and 106 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over HARDING in view of WENZEL as allegedly evidenced by Science Lab.com (Chemicals & Laboratory Equipment). The rejection alleges that HARDING teaches a topical composition to promote the repair of photodamaged skin and/or to reduce or prevent the

damaging effects of ultraviolet light on skin comprising retinol (which allegedly qualifies as antioxidant) or a derivative thereof and a dioic acid of formula COOH-(C_aH_b)-COOH wherein a is an integer from 6 to 20 and b is an integer from 8 to 40. The rejection further alleges that HARDING teaches an effective amount of dioic acid of from 0.1 to 30% by weight, as well as adding an antioxidant such as butylated hydroxytoluene. The Examiner concedes that HARDING does not teach that the dioic acid is 8-hexadecene-1,16-dicarboxylic acid but alleges that this acid would have been obvious to one of ordinary skill in the art since HARDING allegedly teaches hexadecene dioic acid as a predicted product when using oleic acid as a substrate and furthermore, since WENZEL teaches making 8-hexadecene-1,16-dicarboxylic acid using oleic acid as a substrate.

Applicants respectfully disagree with the Examiner in this regard. At any rate, the rejected claims are cancelled, wherefore this rejection is moot.

Further, it is pointed out again that even if only (unbranched) saturated dioic acids are considered the dioic acids acids of HARDING of general formula COOH-(C_aH_b)-COOH wherein a is an integer of from 6 to 20 and b is an integer of from 8 to 40 encompass 15 different acids (with a total of 8 to 22 carbon atoms).

Further, the shortest (unbranched) mono-unsaturated acid (a = 6) already has three isomers, each of which has two stereoisomers (cis- and trans-isomers). The longest (unbranched) mono-unsaturated acid (a = 20) has 10 isomers, each with two stereoisomers. Accordingly, the above formula encompasses a total of 3 + 4 + 4 + 5 + 5 + 6 + 6 + 7 + 7 + 8 + 8 + 9 + 9 +10 + 10 = 101 different mono-unsaturated acids (not taking into account stereoisomers), 8-hexadecene-1,16-dicarboxylic acid being only one example of the altogether 8 (eight) different hexadecene-1,16-

dicarboxylic acids.

Of course, in the case of (unbranched) di-unsaturated dioic acids the number of possible isomers which are encompassed by the above formula is significantly higher. For example, for a = 6, there are already six isomeric di-unsaturated dioic acids (without stereoisomers). For a = 20 there are 108 isomeric di-unsaturated dioic acids (without stereoisomers). Accordingly, the above general formula of HARDING encompasses about thousand different saturated, mono-unsaturated and di-unsaturated dioic acids (without counting stereoisomers).

The rejection does not explain why one of ordinary skill in the art would have had an apparent reason to pick and choose 8-hexadecene-1,16-dicarboxylic acid from the host of different dioic acids which are encompassed by the general formula set forth by HARDING, i.e., an acid which is neither expressly mentioned nor hinted at in this document.

It further is pointed out that unlike for many other dioic acids which are encompassed by the general formula of HARDING, this document fails to provide any indication as to how 8-hexadecene-1,16-dicarboxylic acid can be obtained from either a commercial source or by a synthetic route from readily available starting materials.

For example, according to HARDING C_8-C_{16} saturated dioic acids are available commercially from chemical suppliers (col. 3, lines 28-29) and C_{17}-C_{22} saturated or unsaturated dioic acids can be manufactured by fermentation using certain yeasts (col. 3, lines 30-33).

With respect to C_8-C_{16} unsaturated dioic acids HARDING mentions in col. 3, lines 43-46 that these acids can be produced using the method disclosed in EP 341 796, further details of which are provided in the following passages of this document. According to col. 4, lines 1-26 of

HARDING, it can be predicted that by using oleic acid as a substrate in this method, a mixture of 8 different mono-unsaturated dicarboxylic acids may be produced, whereas linoleic acid is expected to afford a mixture of 13 di-unsaturated dicarboxylic acids and linolenic acid is predicted to afford a mixture of 12 di- and tri-unsaturated dicarboxylic acids. None of these mixtures is expected or predicted to contain any isomer of 8-hexadecene-1,16-dicarboxylic acid. This is yet another reason why HARDING fails to prompt one of ordinary skill in the art to contemplate 8-hexadecene-1,16-dicarboxylic acid as a dioic acid for use in the compositions of HARDING.

Applicants note that the Examiner contends that HARDING allegedly teaches hexadecene dioic acid as a predicted product when using oleic acid as a substrate. In this regard, it is noted that, in col. 4, lines 1-10 of HARDING states (emphasis added):

> If one assumes that there is random removal of C_2 units during beta-oxidation, and that no isomerisation of the products occurs, the following products may be predicted to be formed when using oleic acid as a substrate:
> cis-7-hexadecene dioic acid; cis-5-tetradecene dioic acid; cis-7-tetradecene dioic acid; cis-3-dodecene dioic acid; cis-5-dodecene dioic acid; cis-3-decene dioic acid; cis-5-decene dioic acid and cis-3-octene dioic acid.

While the above passage does mention cis-7-hexadecene dioic acid as one of several predicted products when using oleic acid as a substrate (assuming no isomerization occurs), it is pointed out that 7-hexadecene dioic acid (comprising 16 carbon atoms) and 8-hexadecene-1,16-dicarboxylic acid (comprising 16 + 2 = 18 carbon atoms) are not the same. In this regard, it is noted that Applicants themselves have in the past at times erroneously stated that 8-hexadecene-1,16-dicarboxylic acid comprises 16 carbon atoms when in fact this acid (also known as 9-octadecene dioic acid, as correctly noted by the Examiner at the top of page 5 the instant Office Action)

comprises 18 carbon atoms.

Applicants further note that although WENZEL appears to disclose a fermentation method for making, *inter alia*, 8-hexadecene-1,16-dicarboxylic acid (9-octadecene dioic acid) from oleic acid, WENZEL also makes it clear that this method can reasonably be used only for making a complex mixture of dicarboxylic acids that contains 8-hexadecene-1,16-dicarboxylic acid. In particular, at column 4, lines 7-19 thereof WENZEL states (emphasis added):

> The use of oleic acid substrates having a high oleic acid content which is defined as those substrates having an oleic acid content of equal to or greater than 90% oleic acid produce a very viscous fermentation broth. Fermentation broths having high viscosities have relatively poor heat transfer and oxygen mass transfer. The use of oleic acid substrates having an oleic acid content of less than 90% result in fermentation broths that are less viscous thereby making the maintenance of proper temperature and dissolved oxygen levels much simpler. An example of such an oleic acid is technical oleic acid the composition of which is set forth in Example 1.

In accordance with the above statement the "oleic acid" used in Example 1 of WENZEL is a mixture of monocarboxylic acids having 12, 14, 16 and 18 carbon atoms and from 0 to 3 double bonds that appears to contain about 70 % by weight of oleic acid. It is easy to imagine how complex the mixture of dioic acids resulting from the described procedure must have been. For example, according to col. 6, lines 5-10 of WENZEL this mixture was analyzed (after esterification) by HPLC chromatography. In view of the foregoing facts, Applicants submit that the procedure described by WENZEL clearly is not an incentive for one of ordinary skill in the art to provide a composition according to the teaching of HARDING that contains 8-hexadecene-1,16-dicarboxylic acid.

Applicants submit that at least the totality of the facts set forth above provides evidence that there is no apparent reason for one of ordinary skill in the art to contemplate a dioic acid having 16 carbon atoms and in particular, 8-hexadecene-1,16-dicarboxylic acid for use in providing a

composition according to HARDING.

In this regard, Applicants further remind the Examiner that "[t]he fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious." *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)); see also *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943, *In re Deuel*, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995), and MPEP 2144.08.

In this regard, see also MPEP 2144.08 I.:

When a single prior art reference which discloses a genus encompassing the claimed species or subgenus but does not expressly disclose the particular claimed species or subgenus, Office personnel should attempt to find additional prior art to show that the differences between the prior art primary reference and the claimed invention as a whole would have been obvious. Where such additional prior art is not found, Office personnel should consider the factors discussed below to determine whether a single reference 35 U.S.C. 103 rejection would be appropriate.

Regarding the concentration ranges for 8-hexadecene-1,16-dicarboxylic acid recited in instant claims 126-129, 141 and 142 it is noted that while HARDING discloses general concentration ranges of dioic acid(s) which (slightly) overlap the concentration ranges recited in the instant claims it must be taken into account that the concentration of the dioic acid(s) in the compositions of the various Examples of HARDING is at least 15 % by weight and is in most cases 20 % by weight, i.e., significantly higher than the upper values of the concentration ranges which are recited in the instant claims.

It further is submitted that one of ordinary skill in the art will understand that the broad concentration range for the dioic acids of 0.1 to 30 % given in HARDING for use in conjunction with retinol or a derivative thereof is due to the fact that the general formula of HARDING

encompasses about two thousand different compounds which can be expected to show a broad range of activity. One of ordinary skill in the art will also understand that the fact that HARDING prefers a concentration range of 5 to 20% and employs dioic acids in the compositions exemplified therein in a concentration of not less than 15% reflects the need for sufficient activity of the dioic acids in the compositions disclosed therein.

In this regard, it further is noted that claim 1 of HARDING recites that an effective amount of from 0.1 to 30% by weight of a dioic acid must be employed. Accordingly, HARDING clearly indicates that not each and every dioic acid encompassed by the general formula disclosed therein will be effective (and can be employed) at a concentration of 0.1% but rather teaches that an effective (or at least very desirable) amount in most cases will be at least 15%, i.e., the minimum concentration of dioic acid(s) employed in the Examples of HARDING.

Moreover, a closer analysis of the Examples of HARDING shows that the required (effective) concentration of the dioic acids disclosed therein appears to increase with the number of C atoms. Specifically, the only acids which are employed in a concentration of 15% (see Examples 3 and 9) are azelaic acid (nine carbon atoms) and a C_8 mono-unsaturated dioic acid. All of the other acids (having 12 to 22 carbon atoms) are employed in a (total) concentration of 20%. In view thereof, HARDING may even be considered to teach away from using concentrations of an acid having 18 carbon atoms at a concentration within the ranges recited in the instant claims.

Appellants submit that for at least all of the foregoing reasons, HARDING in view of WENZEL is unable to render it obvious to pick a specific dicarboxylic acid, i.e., 8-hexadecene-1,16-dicarboxylic acid from the about 1,000 dicarboxylic acids encompassed by the general formula

disclosed therein as an acid for use in the compositions of HARDING, let alone in a concentration within the ranges recited in instant claims 8-hexadecene-1,16-dicarboxylic acid.

Response to Rejection under 35 U.S.C. § 103(a) over HARDING in view of WENZELand NACHBAR

Claims 74 and 75 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over HARDING in view of WENZEL and further in view of NACHBAR. The Examiner concedes that HARDING in view of WENZEL does not teach the use of vitamin E as antioxidant but alleges that this deficiency is cured by NACHBAR.

Applicants respectfully disagree with the Examiner in this regard. At any rate, the rejected claims are cancelled, wherefore this rejection is moot as well.

Applicants further note that NACHBAR is unable to cure the deficiencies of HARDING and WENZEL set forth above, wherefore for this reason alone, even a combination of these three documents is unable to render obvious the subject matter of any of the claims submitted herewith.

Response to Rejections based on Nonstatutory Obviousness-Type Double Patenting

Claims 56 and 57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 44 and 55 of copending Application No. 11/087,395. Claims 56 and 57 are also rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1 and 17 of U.S. Patent No. 7,820,177. Further, claims 56 and 57 and additionally claims 74, 75, 96 and 97 are rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1 and 17

of U.S. Patent No. 7,341,712.

Applicants submit that the rejected claims are cancelled, wherefore the above rejections are moot. At any rate, Applicants request that any rejections on the ground of nonstatutory obviousness-type double patenting are held in abeyance until the Examiner has indicated allowable subject matter.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,
Jan BATZER et al.

/Heribert F. Muensterer/

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